Date: Tuesday, September 30, 2003
Enclosures:
Reply to First Office Action and Interview and amendment
Reference article, Byrne et al.

To: Valarie Bertoglio, Ph.D.
Patent Examiner
Art Unit 1632
USPTO

From: Mina Alikani
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Dear Valarie,

Enclosed, please find my reply to First Office Action and telephonic interview. I have also enclosed the reference paper I have cited in the reply. The reply also includes an amendment written on a separate page.

I respectfully request consideration of this reply and the amendment.

Best wishes,

Mina Alikani

Reply to First Office Action and Interview
Application Number 10/036,581
MINA ALIKANI and STEEN M. WILLADSEN
Art Unit 1632
Valerie Bertoglio and Peter Paras, Examiners

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1. Abstract of the disclosure
Please shorten the abstract of the disclosure by deleting lines 6 (starting with the sentence The ICM is...) through line 12 (ending with ...of chorionic gonadotrophin). Total word count after this deletion will be 153 words.

2. 35 USC 101

I feel that the examiners' characterizations that 1) cells from non-viable pre-embryos are themselves viable and appear to embrace human embryos, and therefore encompass viable human embryos; and that 2) these would create a human being , which is non-statutory subject matter are not correct. Chakrabarty v Diamond states very clearly that

"Here, by contrast, the patentee has produced a new bacterium with markedly different characteristics from any found in nature and one having the potential for significant utility. His discovery is not nature's handiwork, but his own; accordingly it is patentable subject
matter under § 101".

Therefore, I feel that one only has to substitute the words non-viable pre-embryos for bacterium to see that this is patentable subject matter under USC 101.

The other issue discussed is whether these artificial composite non-viable pre-embryos can become "human beings" and therefore fall under subject matter that would be non-patentable under USC 101. These artificial composite non-viable pre-embryos cannot become viable and are not functional if implanted and therefore cannot become even fetuses less viable "human beings".

In specific, In claims 1-6 and 7 and 8 (page 4 of the published patent application--), the broadest reasonable interpretation of the claimed invention does not encompass a human being, but encompasses non-viable human pre-embryos which provide the components of a composite non-viable pre-embryo

which is a non-naturally occurring "assembly of parts" (see appendix 1) and will give rise to a non-viable composite human blastocyst from which viable stem cells can be derived. The non-viable composite human blastocyst is a "human creation for human ends" (see appendix 1); it is an "entity that lacks the qualities and capabilities essential to be designated a human life in process" (see appendix 1). Therefore, it can not be transferred to the uterus because it is chimaeric, thus abnormal, and it also may contain many chromosomally abnormal cells. Therefore the non-viable composite human blastocyst is "intrinsically limited" (see appendix 1) and has no chance of giving rise to a human. Even if it were to be transferred to a uterus, it is not expected to be viable or give rise to a human being.

In addition, the MPEP, on page 2100-4, states: A "non-naturally occurring manufacture or composition of matter—a product of human ingenuity—having a distinctive name, character, and use" is patentable subject matter.

Therefore the composite blastocyst is patentable subject matter.

3. 35 USC 112 para 1

Claims 1-13 encompass non-mammalian species. I am attaching a reference paper entitled, "From intestine to muscle: Nuclear reprogramming through defective cloned embryos", by Byrne et al., PNAS, April 2002, on duplicating our work, after our filing, using composite cloned frog embryos. They therefore show enablement of the aggregation process for non-mammalian embryos. It is also not prior art to this application filing or disclosure document date of conception.

4. 35 USC 112 Para 2

I define the term pre-embryo as pre-blastocyst, to satisfy rejection 112 para 2. Please add the sentence---Pre-embryo is defined as pre-blastocyst in section BACKGROUND, para 0003, line 5, of the published patent application.

It is my understanding that an inventor can be his or her own lexicographer and define terms that may be of different meaning but not repugnant to their ordinary meaning MPEP 706.03(d). I do not feel that this usage is repugnant to their ordinary meaning in either the specification or the claims.

5. 35 USC 102b

The MPEP, on page 700-21, states, "For anticipation under 102, the reference must teach every aspect of the claimed invention either explicitly or impliedly. Any feature not directly taught must be inherently present." Therefore, with regards to Luo and Nagy teachings, I feel that our claims are patentably distinguishable from the prior art and that the references do not teach every aspect of the claimed invention.

The teachings of Nagy et al. are: 1) ES cell based genetic manipulation, and 2) Optimal in vitro culture conditions for retaining the initial totipotency of ES cells. Luo teachings do not include the cells discussed in our specifications, namely, single-nucleated cells taken from several non-viable discarded dissociated human pre-embryos (Section BRIEF SUMMARY OF THE INVENTION, Para 0015, lines 13 and 14 of the published patent application), aggregated together to make a composite pre-embryo—Luo teachings only discuss 1) tetraploid cells, 2) non-human cells, and 3) normal whole embryos aggregated together. Therefore, Luo does not teach every aspect of our claims, neither is every aspect inherently present or suggested.

With regard to Thompson, viable fresh or frozen-thawed donated human embryos were used (Examiners' reference, Science 1998, Vol 282, page 1147 under section 'references and notes' number 6) and non-composite, ordinary blastocysts that developed in culture (not manufactured) from these viable (not non-viable) human embryos were used. His teaching does not include stem cells derived from composite blastocysts from non-viable discarded human pre-embryos.

Furthermore, in the case of human embryonic stem cells, it is indeed the source of the stem cells that is at the center of much debate and controversy. For instance, it is the source of the embryonic stem cells that determines whether the research on stem cell lines is funded by the US NIH. Creation of new pre-embryos through in vitro fertilization (IVF) of human eggs or use of viable pre-embryos left over from IVF procedures excludes the research from funding by the NIH unless the lines were established prior to August 9, 2001. Creation of new human pre-embryos or use of viable human pre-embryos for derivation of stem cells has been deemed unacceptable by the President of the United States on moral grounds (President Bush's address to the nation on August 9, 2001). Therefore, in this context, and with regard to our specification, the source of the stem cells takes on great importance and relevance. That Thomson used viable

fresh or frozen-thawed human pre-embryos left over from IVF procedures to isolate stem cells establishes great distinction between his work and ours.

6. I feel that the examiners statement: "It is only the product, which is anticipated by the prior art and not the process by which the product was made. This is because the final product (a stem cell line) is not distinguished by any particular features or characteristics resulting from the process by which it is made. As such, the limitations of the claimed stem cell line are met by any stem cell line in prior art" is not correct.

   We claim "composite blastocyst-derived stem cells". A "composite blastocyst-derived" stem cell line is not anticipated, as the element "composite blastocyst", or the combination of stem cells and "composite blastocyst" is not anticipated, nor described, nor obvious to one of ordinary or expert skill in the art. Indeed, it is the process that defines the product in this case and both are novel and represent a paradigm shift in human embryology: Non-viable pre-embryos are routinely discarded in IVF laboratories in the United States as well as other parts of the world. To use such pre-embryos for derivation of stem cells is a novel concept that never before has been proposed or attempted since non-viable embryos are not expected to give rise to stem cell lines. It is the process of aggregation in the form described in the specification that artificially brings about such capability. It is therefore both the process and the product that are patent-worthy. This is completely contrary to the Examiners' telephone statement that "the process by which the stem cells are derived carries little patentable weight."

   In addition, products defined by their process of manufacture or isolation are common patentable subject matters. For example, in all the PCR patents, there are claims to a Taq polymerase being a polymerase derived from the thermophillic bacterium Thermus Aquaticus. That is, "Thermus Aquaticus - derived DNA polymerase" is proper written description under 112 para 1 and also patentable under 101. Accordingly, "composite blastocyst-derived stem cells" are no different and do not require any structural characteristics to define them. This is similar to Taq polymerase which doesn't require a structural sequence definition to make it patentable.

7. Black and white photographs will be submitted.